REMARKS

I. Status of Claims

Applicants thank the Examiner for the very thorough consideration given the present application. Claims 11, 14-15 and 20-23 are currently pending in this application. Claims 1-10, 12, 13, 16-19, 24 and 25 were previously canceled. Claim 26 is newly canceled.

Claim 11 has been amended to recite the subject matter of canceled claim 26. Claims 11, 15 and 23 have been amended for clarity. No new matter has been added by way of the present amendment.

In view of the amendments and remarks herein, Applicants respectfully request that the Examiner withdraw all outstanding rejections and allow the currently pending claims.

II. Claim Objections

The Examiner makes specific objections to the language of claims 11, 15 and 23. In response, Applicants have amended claims 11, 15 and 23 for clarity addressing the Examiner's objections. As such, withdrawal of the objections is respectfully requested.

III. Prior Art Based Issues

The following rejections are pending:

> (A) Clams 11, 14-15 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makoto et al. (JP 2001-327609) in view of Nishikawa et al. ("Fabrication of Honeycomb Film of an Amphiphilic Copolymer at the Air-Water Interface"), and further in view of Masaru et al. (JP 2003-149096); and
>
> (B) Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makoto et al. in view of Nishikawa et al. and Masaru et al., as applied above, and further in view of Lawin et al. (US 2004/0111144 A1).

Applicants respectfully traverse these rejections. The rejections are hereinafter referred to as Rejections (A) and (B), respectively.

III – A. Rejection (A)

Without conceding that Rejection (A) is proper, Applicants have amended claim 11 to recite the subject matter of claim 26. As such, Rejection (A) is rendered moot.

Applicants now discuss Rejection (B).

III – B. Rejection (B)

In Rejection (B), the Examiner combines Makoto et al., Nishikawa et al., Masaru et al., and Lawin et al. in order to find claim 26 obvious.

The Examiner admits at page 5, 3rd full paragraph that Makoto et al. and Nishikawa et al. fail to teach the weight ratio of the amount of the non-biodegradable resin (1,2-polybutadiene) to the amount of the amphiphilic substance being 99:1 to 50:50. For this feature, the Examiner relies on Masaru.

However, this combination of references is improper, since the skilled artisan would not look to Masaru et al. in order to modify the teachings of Makoto et al. as asserted by the Examiner.

The Examiner states that Makoto teaches a biliary stent designed to prevent invention of tissue into the film and stent. "Thus the film of the Makoto is cell-growth-inhibiting film." See page 4, 3rd full paragraph of outstanding Office Action. However, this is distinct from Masaru et al. wherein a **blood filtration membrane** is described as having a pore size of 0.5 to 40 μm and a coefficient of variation in pore size of 20% or less.

Applicants respectfully submit that the artisan would not look to the specifics of the blood filtration membrane of Masaru et al. in order to modify the stent of Makoto et al.

Furthermore, the medical instrument of the present invention is an instrument in which the stem substrate is covered with a specific porous film, and completely differs in application and usage from the blood filtration membrane disclosed in Masaru et al. As such, significant patentable distinctions exist between the present invention and the teachings of Makoto et al. and Masaru et al.

With respect to inventive claim 26, the Examiner relies on Lawin et al. for teaching the use of 1,2-polybutadiene in the film formed on a surface of the medical instrument substrate. At the paragraph numbered as "6" at page 7 of the outstanding Office Action, the Examiner states:

> Regarding claim 26, as explained supra, Makoto, Nishikawa, and Masaru combination broadly teach the non-biodegradable resin to be a polyolefin polymer.
>
> Makoto, Nishikawa, and Masaru combination fail to explicitly teach the polyolefin polymer to specifically be 1,2-polybutadiene.
>
> However, Lawin et al (Lawin) teaches a stent comprising a polyolefin film, specifically 1,2-polybutadiene ([0019]).

However, Applicants respectfully submit that the skilled artisan would not use the 1,2-polybutadiene resin in the film formed on a surface of the medical instrument substrate of Makoto et al. as asserted by the Examiner.

Lawin et al. disclose an implantable medical device including a polymeric coating that releases a bioactive agent from the surface of the device *in vivo*. Lawin et al. disclose coating a stent with a polymer. However, this polymer merely serves as a barrier, and does not have a filtration function (i.e., a function of allowing a specific liquid to pass through while blocking only a specific substance using a porous membrane). Therefore, a person skilled in the art could not have arrived at combining Lawin et al. with the other cited references (Makoto et al., Nishikawa et al. and Masaru et al).

Furthermore, the Examiner will note that the present invention has unexpected results over the teachings of the cited references (Makoto et al., Nishikawa et al. and Masaru et al). A person skilled in the art could not have expected that the coefficient of variation in pore size can be reduced using 1,2-polybutadiene as the stent cover film as compared with the case of using another resin (polyurethane) (see Table 3 of the present application).

Accordingly, Rejection (B) is not tenable. Reconsideration and withdrawal of Rejection (B) are respectfully requested.

III – C. Patentability of claims 21-23

Applicants note that claims 21-23 are patentable over the teachings of the cited references for the same reasons set forth above. However, claims 21-23 which are drawn to a digestive system stent are further patentable for the following reasons:

Applicants note that Makoto et al. is described in the present specification at paragraph [0006]. According to the present inventors, Makoto et al. teach a covered stent which is useful for preventing stricture of a tubular cavity in the body due to the growth of cancer cells or the like, since the resin film does not allow the cancer cells to pass through. However, since the film used for the covered stent cannot allow digestive fluids such as pancreatic juice to pass through, the flow of the digestive fluid is hindered due to the covered stint, whereby a serious system such as pancreatitis may occur. See paragraph [0007] on page 2 of the present specification.

Unobviousness can reside in the discovery of the cause of a problem, the solution of which employs a combination of old elements. *In re Sponnoble* (CCPA 1969) 405 F2d 578, 160 USPQ 237. Applicants note that Nishikawa et al. teach the use of a fabrication of a honeycomb film of an amphiphilic copolymer at the air-water interface. These films are taught to be used as cell culture substrates. Applicants also note that there is no teaching or suggestion by either Makoto et al. or Nishikawa et al. that there is a problem in that the flow of digestive fluid is hindered due to the covered stent thereby causing pancreatitis. The skilled artisan would not recognize this problem from the teachings of Makoto et al. and Nishikawa et al. Furthermore, the skilled artisan would not recognize that incorporating the honeycomb film of Nishikawa et al. into the stent of Makoto et al. would solve this problem.

It is unclear from the Examiner's comments in the outstanding Office Action, whether the Examiner has considered the fact that this problem was not known at the time of the invention. As such, Applicants respectfully request that the Examiner acknowledges in the next communication that claims 21-23 are patentable over the cited references.

IV. Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and objections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Garth M. Dahlen, Ph.D., 43,575 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated:

NOV 05 2010

Respectfully submitted,

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